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10/811,589	03/29/2004	Eric Tomasetti	TR-6132 (BXTC 4021)	2100
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Mr. Joseph B. Barrett Baxter Healthcare Corporation One Baxter Parkway, DF3-2W Deerfield, IL 60015				
EXAMINER				
MCLELLAND, KIMBERLY KEIL				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,589

Applicant(s)

TOMASETTI ET AL.

Examiner

KIMBERLY K. MCCLELLAND

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 2/28/08, 3/01/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Inventor's Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-17 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added phrase, "wherein the electromagnetic beam does not directly contact the tubing sections" is not found to have support in paragraphs 0036-0037, 0040, or 0042. While clearly disclosing applying the laser to the absorbing member, there is no disclosure in the application as filed for the electromagnetic beam not coming into direct contact with the tubing sections. The mere

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absence of a positive recitation in the original specification is not basis for the exclusion of a feature. *Ex Parte Grasselli* 231 USPQ 393,394. (Bd. App. 1983). Consequently, the newly added language is considered new matter. Claims 2-17 and 23 are rejected due to their dependency on independent claim 1.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-17 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: providing a material for absorbing energy at the ends of the tubing sections for fusing. Claim 1 requires directing an electromagnetic beam towards the tubing sections without directly contacting the tubing sections. This step is not possible unless another material is present to absorb the energy directed at the tubing sections. Consequently, the missing step of providing an absorbing material is necessary to accurately describe the invention. Claims 2-17 and 23 are rejected due to their dependency on independent claim 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9,16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer and U.S. Patent No. 6,596,122 to Savitski et al.

9. With respect to claim 1, Yang et al. discloses a method for connecting flexible tubing wherein the tubing is placed in an axial end-to-end position (See Figures 2A and 2B), using a laser directed to heat the tube ends (paragraph 0068), and bringing them into contact with each other (paragraph 0071). However, Yang et al. does not specifically disclose maintaining interior passages of the two tubing sections so as to be free from exposure to the surrounding environment until and during welding or the electromagnetic beam does not directly contact the tubing sections.

10. Spencer discloses an apparatus for welding together two sections of tubing, including a method of welding two tubing sections together and maintaining interior passages of the two tubing sections so as to be free from exposure to the surrounding environment until and during welding (See Figures 5-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the tubing sections free from exposure to the environment until and during welding as taught by Spencer in the method of Yang et al. The motivation would have been to prevent contamination in the tubing or patient (column 5, lines 25-27).

11. Savitski et al. discloses a method of joining pipes, including it is known in the art to apply radiation to a joint interface such that the beam either directly contacts the tubing sections or does not directly contact the tubing sections by providing an intervening absorbing member (See Figures 1-3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the beam contacting only the absorbing member as taught by Savitski for the beam focused on the tube ends as disclosed by Yang. The motivation would have been to improve weld strength (column 2, lines 1-9). It is known that to improve weld strength, electromagnetic beams may be directed to an energy absorbing material, instead of the joining substrates. It would have been obvious to use a known step of increasing weld strength to improve a similar method, by not contacting the tube ends with the electromagnetic beam, in the same way.

12. As to claim 2, Yang et al. is silent as to the temperature of the tubing ends before the laser is activated. However, in order for the tubing to be in a solid state prior to the welding process, the temperature of the tubing ends must be below the melting temperature of the material forming the tubing section. Yang et al. discloses that the laser melts the tubing (paragraph 0069).

13. As to claim 3, Yang et al. discloses the use of a material (film) to absorb energy from the laser at the tube ends (paragraph 0072).

14. As to claim 4, Yang et al. discloses a sheet of material (film), which has a high concentration of dye to absorb energy of the laser (paragraph 0072).

15. As to claim 5, Yang et al. discloses that the tubing material is substantially transparent (not laser responsive) to the electromagnetic beam (paragraph 0127).
16. As to claim 6, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071) and flow outward when heated (paragraph 0072).
17. As to claim 7, Yang et al discloses that dye may be applied to the tube ends (areas to be joined) that are welded by the laser (paragraph 0129).
18. As to claim 8, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071).
19. As to claim 9, Yang et al. discloses a method for connecting two pieces of tubing as disclosed above. Yang et al. also discloses that all the welding method is carried out in the axial position (See Figures 4A-4F). However, Yang does not disclose cutting off end portions of the tubing sections.

20. Spencer discloses an apparatus for welding together two sections of tubing, including a method of cutting of end sections of tubing prior to welding (column 3, lines 14-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of cutting the tubing sections prior to welding, as taught by Spencer, with the laser welding method of Yang et al. in the axial position in order to ensure proper connection during welding.

21. As to claim 16, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071), and flow outward (paragraph 0072).

22. As to claim 17, Yang et al. discloses that a laser is directed at the tube ends (paragraph 0068).

23. Claims 10-15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. and Spencer and U.S. Patent No. 6,596,122 to Savitski et al. as applied to claims 1-9,16, and 17 above, and further in view of U.S. Patent No 4,832,773 to Shaposka et al.

24. Yang et al., Spencer, and Savitski disclose a method of welding tubing sections together. Spencer also teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40). However, Yang et al., Spencer, and Savitski et al. do not disclose the clamping of the tubing.

25. As to claim 10, Shaposka et al. discloses a method for connecting sections of tubing, including clamping the cut (pre-cut) tubing sections (column 3, lines 48-51). It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to use a method of clamping the tubing sections, as taught by Shaposka et al., with the laser welding method of Yang et al. and Spencer to keep the tubing sections stationary.

26. As to claim 11, Yang et al. discloses sealing the tube ends prior to welding the tubing sections together (paragraph 0072).

27. As to claim 12, Yang et al. discloses the use of a weld block (drum head) to absorb energy from the laser and combine with the tube (paragraph 0072).

28. As to claim 13, Spencer teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40).

29. As to claim 14, Spencer teaches the movement of welded tubing (weld sample) from one location (device) to a remote location (vise column 3, line 62- column 4, line 12).

30. As to claim 15, Yang et al. discloses that all the welding method is carried out in the axial position (See Figures 4A-4F).

31. As to claim 23, Yang et al. discloses the step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces of the of the tubing sections (See Yang et al. paragraph 0066), wherein the sheets are capable absorbing the energy of the electromagnetic beam (See Yang et al. paragraph 0072).

32. Claims 18-20, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,596,122 to Savitski et al. in view of U.S. Patent No. 4,793,880 to Shaposka et al.

33. With respect to claim 18, Savitski et al. discloses a pipe joining method, including providing at least a portion of the tubing section; placing the portion of the tubing section in contact with an energy absorption member; directing a beam of electromagnetic energy onto the energy absorption member, the energy absorption member being constructed for absorbing energy from the beam; and transferring heat from the energy absorption member to the tubing section portion by contact therewith to melt and seal the tubing section portion (See Abstract; column 9, line 49-column 10, line 3). However, Savitski et al. does not specifically disclose collapsing the tubing portion, such that a collapsed portion of the tubing section extends past the clamped portion, and sealing the tubing section in its collapsed configuration.

34. Shaposka et al. discloses a sterile welding method, including collapsing at least a portion of the tubing section such that a collapsed portion of the tubing section extends past the clamped portion, prior to sealing, and sealing the collapsed tubing section portion in its collapsed configuration (See Figures 24, 25, 27, 46, and column 8, lines 44-47). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the clamping and collapsing step of Shaposka et al. with the joining method of Savitski et al. The motivation would have been to exclude most of the fluid from the weld zone (Shaposka, column 1, lines 13-15).

35. As to claim 19, Savitski et al. discloses the energy absorption member has low thermal conductivity (i.e. plastic; column 4, lines 14-22).

36. As to claim 20, Savitski et al. discloses the energy absorption member comprises a block (44; See Figure 3).

37. As to claim 22, Savitski et al. discloses the energy absorption member is a film (column 4, lines 14-22).

38. As to claim 24, Savitski et al. discloses the tubing section is an end in the tubing section (See Figure 1). However, Savitski et al. does not specifically disclose collapsing the tubing portion, such that a collapsed portion of the tubing section extends past the clamped portion, and sealing the tubing section in its collapsed configuration.

39. Shaposka et al. discloses a sterile welding method, including collapsing at least a portion of the tubing section such that a collapsed portion of the tubing section extends past the clamped portion, prior to sealing, and sealing the collapsed tubing section portion in its collapsed configuration (See Figures 24, 25, 27, 46, and column 8, lines 44-47). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the clamping and collapsing step of Shaposka et al. with the joining method of Savitski et al. The motivation would have been to exclude most of the fluid from the weld zone (Shaposka, column 1, lines 13-15).

40. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,596,122 to Savitski et al. in view of U.S. Patent No. 4,793,880 to Shaposka et al. as applied to claims 18-19, 22, and 24 above, and further in view of U.S. Patent Application Publication No. 2003/0226631 to Sterud et al.

41. With respect to claim 21, Savitski et al. discloses a pipe joining method, including an energy absorption member (40; See Figure 1). Savitski also discloses the energy

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absorption member is a black plastic (column 4, lines 14-22). However, Savitski et al. does not teach the use of glass or polytetrafluoroethylene energy absorption members.

42. Sterud discloses a welding method, including using weld blocks (sleeve) of glass or polytetrafluoroethylene (See Paragraph 0086). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the glass or polytetrafluoroethylene taught by Sterud et al. with the sleeve of the tubing sealing method of Savitski et al. to use amore rigid material, and ease movement of the tubing in the sleeve (See paragraph 0086).

Response to Arguments

43. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection were necessitated by the current amendment and newly provided prior art U.S. Patent No. 6,596,122 to Savitski et al. Applicant's remaining pertinent arguments are addressed below:

44. As to applicant's argument that Yang does not disclose the electromagnetic beam does not contact the tubing sections, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KIMBERLY K. MCCLELLAND whose telephone number is (571)272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Thr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip C. Tucker can be reached on (571)272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. K. M./
Examiner, Art Unit 1791

KKM

/Philip C Tucker/

Supervisory Patent Examiner, Art Unit 1791